

Areas within Vancouver Coastal Health (VCH) that will be impacted by the research study -- select all that apply:

- ☐ **VCH-Vancouver (Vancouver Acute):** Vancouver General Hospital, Diamond Health Care Centre, Mary Pack Arthritis Centre, G.F. Strong Rehabilitation Centre, UBC Hospital, Blusson Spinal Cord Centre (ICORD), VGH Research Pavilion and the Burnaby Centre for Mental Health and Addiction.
- ☐ **VCH-Vancouver (Vancouver Community):** Community health centres, mental health centres, addiction sites and residential care facilities owned and operated by Vancouver Coastal Health (Banfield, Dogwood Purdy and George Pearson).
- ☐ **VCH-Coastal:** Hospitals, community health centres and residential care facilities in North Vancouver, West Vancouver, Garibaldi, Powell River/Sunshine Coast, Sea to Sky Corridor, including Bella Bella and Bella Coola.
- ☐ **VCH-Richmond (f. Richmond Health Services):** Encompasses the following networks: Richmond acute care, community care, primary health care, mental health and addiction sites.
- ☐ **VCH Corporate Research Project:** Projects involving, for example, surveys of VCH staff located across multiple health service delivery areas.

1. Research Study Title (and Protocol Number, if applicable):

2. Investigator:

Name:
Address:

Tel:
Fax:
Email:

3. Department:

Division:

4. VCH Collaborator (if applicable):

5. Primary Contact Person:

Name:
Tel:
Fax:
E-mail:

6. Internal Mailing Instructions / Address:

7. Type of Funding Source: ☐ Industry ☐ Grant ☐ Grant-in-Aid ☐ Unfunded ☐ Other

8. Name of Funding Source(s):

9. Type of Study: ☐ Drug/Natural Health Product Study ☐ Medical Device Study ☐ Chart Review ☐ Intervention Outcome
☐ Other: *If a drug/natural health product will be administered to human subjects, obtain a signature of approval on this form from each applicable HSDA Pharmacy Department. Manager.*

10. P.I.'s VCH Department Head:

(print name) (signature) (date)

11. P.I.'s VCH Division Head (if applicable):

(print name) (signature) (date)

12. P.I.'s Supervisor/Manager: (See Guidance Notes – Applicable to VCH employees only.)

(print name) (signature) (date)

13. Principal Investigator:

(print name) (signature) (date)

FOR VCHRI USE ONLY (do not complete)

VCHRI Project #: _____

Date Received: _____

HSDA	Sent for Review	Approved
VA		
VC		
RHS		
Coastal		

14. ☐ VCH-Vancouver (Vancouver Acute)

A. Department approvals.			B. Approval signatures required.			C. Department cost analysis.	
Department	Yes	No	VGH Site Name of Signatory	UBC Hospital Site Name of Signatory	Signature	Yes	No
Pharmacy	☐	☐				☐	☐
Radiology (MRI, CT, x-ray, ultrasound, etc.)	☐	☐				☐	☐
Clinical Chemistry	☐	☐				☐	☐
Microbiology	☐	☐				☐	☐
Operating Rooms	☐	☐				☐	☐
Anesthesia	☐	☐				☐	☐
Anatomical Pathology	☐	☐				☐	☐
Hematopathology	☐	☐				☐	☐
Clinical Unit (1):	☐	☐				☐	☐
Clinical Unit (2):	☐	☐				☐	☐
Decision Support	☐	☐				☐	☐
Health Records (hard copy)	☐	☐				☐	☐
VCH database: (e.g. PACS, ORMIS, PCIS)	☐	☐				☐	☐
Other database:	☐	☐				☐	☐
Other Resources: (Specify)	☐	☐				☐	☐

☐ VCH-Vancouver (GF Strong Rehabilitation Centre)

For information on GF STRONG signatories, please contact Elaine Pozney at elaine.pozney@vch.ca or (604) 737-6208.

A. GF Strong departmental approvals.			B. Approval signatures required from relevant Medical/Program Director or Manager.		C. Department cost analysis.	
Department	Yes	No	GF Strong Site Name of Signatory	Signature	Yes	No
Adult Learning	☐	☐			☐	☐
Assistive Technology	☐	☐			☐	☐
Decision Support	☐	☐			☐	☐
Driver Rehab	☐	☐			☐	☐
Equipment Evaluation	☐	☐			☐	☐
Facility Operations (e.g. space – please specify)	☐	☐			☐	☐
Health Records (hard copy)	☐	☐			☐	☐
Medicine (EMG, Radiology, Baclofen Clinic, Library)	☐	☐			☐	☐
Nursing	☐	☐			☐	☐
Nutrition & Food Services	☐	☐			☐	☐
Occupational Therapy	☐	☐			☐	☐
Physiotherapy	☐	☐			☐	☐
Pharmacy	☐	☐			☐	☐
Psychology	☐	☐			☐	☐
Recreation Therapy	☐	☐			☐	☐
Sexual Health	☐	☐			☐	☐
Social Work	☐	☐			☐	☐
Speech-Language Pathology	☐	☐			☐	☐
Vocational Rehab Service	☐	☐			☐	☐
Other Resources:	☐	☐			☐	☐

☐ VCH-Vancouver (Vancouver Community)

For information on Vancouver Community signatories, please contact Donna Costello at donna.costello@vch.ca or (604) 708-5253

A. Name of Vancouver Community Site	B. Approval signatures required.		C. Department cost analysis.	
	Site Manager	Director	Yes	No
	Name: Signature:	Name: Signature:	☐	☐
	Name: Signature:	Name: Signature:	☐	☐
	Name: Signature:	Name: Signature:	☐	☐
	Name: Signature:	Name: Signature:	☐	☐
	Name: Signature:	Name: Signature:	☐	☐
	Name: Signature:	Name: Signature:	☐	☐
	Name: Signature:	Name: Signature:	☐	☐
VCH Database: PARIS (if applicable)	Name: Signature:	Name: Signature:	☐	☐
Other Database: (if applicable)	Name: Signature:	Name: Signature:	☐	☐

☐ **VCH-Coastal**

Coastal Contact (name):

Tel: Email:

A. Coastal HSDA department approvals.			B. Approval signatures required.		C. Department cost analysis.	
Hospital: ☐ N/A	Yes	No	Hospital Site Manager Name of Signatory	Signature	Yes	No
Pharmacy	☐	☐			☐	☐
Radiology (MRI, CT, x-ray, ultrasound, etc.)	☐	☐			☐	☐
Clinical Chemistry	☐	☐			☐	☐
Microbiology	☐	☐			☐	☐
Operating Rooms	☐	☐			☐	☐
Anatomical Pathology	☐	☐			☐	☐
Hematopathology	☐	☐			☐	☐
Clinical Unit/Site/Program Area (1):	☐	☐			☐	☐
Clinical Unit/Site/Program Area (2):	☐	☐			☐	☐
Clinical Unit/Site/Program Area (3):	☐	☐			☐	☐
Decision Support	☐	☐			☐	☐
Health Records (hard copy)	☐	☐			☐	☐
VCH database: (e.g. PACS, ORMIS)	☐	☐			☐	☐
Other database:	☐	☐			☐	☐
Other Resources: (Specify)	☐	☐			☐	☐

A. Name of Coastal Community Site or Program Area	B. Approval Signatures Required.		C. Department cost analysis.	
	Name of Signatory	Signature	Yes	No
			☐	☐
			☐	☐
			☐	☐
			☐	☐

☐ **VCH-Richmond (f. Richmond Health Services)**

Richmond Health Services Contact (name):

Tel: Email:

Please complete the VCH-Richmond Impact Analysis Form for each Richmond department/clinic a research project will impact. A Richmond department head or manager signature is required on the Impact Analysis Form. This is a VCH-Richmond site specific requirement.

A. Richmond Health Services department approvals.			B. Approval signatures required.		C. Impact analysis.	
Department	Yes	No	Department Head	Program Manager	Yes	No
Acute Care Specify Department	☐	☐	Name: Signature:	Name: Signature:	☐	☐
Community Care Specify Department	☐	☐	Name: Signature:	Name: Signature:	☐	☐
Primary Care Specify Department	☐	☐	Name: Signature:	Name: Signature:	☐	☐
Health Records (hard copy)	☐	☐	Name: Signature:	Name: Signature:	☐	☐
Decision Support	☐	☐	Name: Signature:	Name: Signature:	☐	☐
VCH Databases	☐	☐	Name: Signature:	Name: Signature:	☐	☐
Other Resources: (Specify)	☐	☐	Name: Signature:	Name: Signature:	☐	☐

☐ **VCH-Corporate**

A. Name of Corporate Site or Department	B. Name and Signature of Corporate Site or Department Director/ Manager.		C. Department cost analysis.	
	Name of Signatory	Signature	Yes	No
			☐	☐
			☐	☐
			☐	☐
			☐	☐

15. STUDY PERSONNEL:

a) The Principal Investigator on this research study (one of the following must apply):

1. Has a medical appointment within VCH
2. Is an employee of VCH (e.g., nurse, respiratory therapist, manager)
3. Is a VCHRI researcher
4. Is a VCHRI Affiliated Investigator
5. Is in the process of applying for a VCH Affiliated Investigator Appointment

☐ Yes ☐ No
☐ Yes ☐ No
☐ Yes ☐ No
☐ Yes ☐ No
☐ Yes ☐ No

***If the Principal Investigator has a VCHRI Affiliated Investigator Appointment, he/she must have a VCH Collaborator named on the research study (the VCH Collaborator must be listed on the REB application as a Co-Investigator or Study Team member).

***If the Principal Investigator does not fall under one of the above categories, please contact Stephanie Manusha at (604) 875-5649 or stephania.manusha@vch.ca

b) If the Principal Investigator is a VCH employee, please indicate:

(i) Which professional discipline the Principal Investigator is a member:

- | | | |
|---|---|--|
| ☐ Audiology | ☐ Occupational Therapy | ☐ Speech Language Pathology |
| ☐ Clinical Nutrition | ☐ Pharmacy | ☐ Spiritual Care |
| ☐ Dentistry | ☐ Physiotherapy | ☐ Other: |
| ☐ Diagnostic Imaging | ☐ Psychology | |
| ☐ Laboratory | ☐ Recreation Therapy | |
| ☐ Music Therapy | ☐ Respiratory Therapy | |
| ☐ Nursing | ☐ Social Work | |

☐ N/A

(ii) Whether their position is at a Manager/Director level.

☐ N/A
☐ Yes ☐ No

c) Will research personnel **not employed by /affiliated with** VCH (e.g. volunteer research assistants, research personnel affiliated with external institutions) participate in the conduct of this study? If YES, please **name** and briefly describe their roles:

16. ACCESS TO PERSONAL INFORMATION:

a) Will you or any of your research team members access identifiable personal information of VCH patients/clients/residents/staff in this research study?

☐ Yes ☐ No

If YES, each research team member must sign the "Confidentiality Undertaking for Research Projects" form (see **Attachment A**).

17. DECISION SUPPORT AND HEALTH RECORDS

a) Will this research study involve the services of Decision Support? (If YES, obtain a signature of approval from Decision Support on this form.)

☐ Yes ☐ No

b) Will you require access to patient medical records (charts) located in a VCH Health Records Department? (If YES, obtain a signature of approval from the appropriate Health Records Department on this form.)

☐ Yes ☐ No

c) Will you review patient medical records (charts) located in a clinician's office, hospital clinic/ward/department or community site located within Vancouver Coastal Health?
d) If YES to (c), advise where the patient records are located:

☐ Yes ☐ No

Obtain a signature of approval from the clinician's office, hospital clinic/ward/department or community site for access to the records.

e) If you are accessing health records/receiving data from Decision Support, will contact information of patients be extracted/provided and used for subject recruitment purposes?	☐ N/A ☐ Yes ☐ No ☐ Yes ☐ No
If YES, have the patients consented to be contacted for future research?	

18. DATABASES	
a) Will you require access to a <u>VCH database or clinical system</u> (e.g. PACS, ORMIS, PARIS etc.)?	☐ Yes ☐ No
If YES: (1) List the database(s) you will require access to: (2) Complete the "Data Access For Research Application Form" located on the VCHRI website. (3) Obtain a signature of approval to use the database for research purposes from the appropriate VCH department.	
b) Will you require access to any <u>internal department/program databases</u> (e.g. orthopedic-trauma database)?	☐ Yes ☐ No
If YES, which internal database(s)? Obtain a signature of approval from the department/individual responsible for the database on this form.	☐ Yes ☐ No
c) If you are accessing a database/a clinical system in this study, will contact information of patients be extracted and used for subject recruitment purposes?	☐ N/A ☐ Yes ☐ No ☐ Yes ☐ No
If YES, have the patients consented to be contacted for future research?	

19. STUDY PROCEDURES/ASSESSMENTS:	
For research studies that <u>do not</u> involve the participation of human research subjects or the utilization of VCH Anatomical Pathology diagnostic material (e.g. slides, tissue blocks or tissue procurement), this section is not applicable.	
a) Will research subject recruitment occur on a hospital ward/clinic/community site? (If YES, a signature of approval from the patient service manager/clinic manger of <u>each</u> hospital ward/clinic/community site must be obtained.)	☐ Yes ☐ No
If YES, list the hospital ward(s)/clinics/community sites where research subjects will be recruited from:	
b) <u>Where</u> will subject informed consent be obtained? (NOTE: If informed consent will be obtained on a hospital ward/clinic/community site, a signature of approval from the applicable patient service manager/clinic manager must be obtained.)	
c) Will any research study visits/assessments/ take place on a hospital ward/clinic/community site? (If YES, a signature of approval from the patient service manager of <u>each</u> hospital ward/clinic/community site impacted must be obtained.)	☐ Yes ☐ No
d) If a questionnaire will be administered, where will this occur?	☐ N/A
e) If a focus group will be held or interview conducted, where will this occur?	☐ N/A
f) Will research subjects undergo any surgical procedures in the <u>OPERATING ROOM</u> ?	☐ Yes ☐ No
If YES, a signature of approval from the Operating Room* must be obtained on this form. Prior to signing off on this form, the OR must receive a completed "OR Research Form" and a copy of the study protocol. Indicate which operating room locations will be impacted by the research: ☐ VGH ☐ UBCH ☐ Other:	
*The Operating Room Manager of Equipment and Supplies or Patient Service Manager must sign this form.	

g) Will tissue specimens be collected from subjects in the <u>OPERATING ROOM</u>? If YES, both the Operating Room and Anatomical Pathology must review the study. STEP 1: Anatomical Pathology must review the following documents: (a) research study protocol; (b) the “Anatomical Pathology Laboratory Utilization Form”; and (c) the “Specimen for Research Collection – Special Handling Instructions” form and sign the “Request for Approval to Conduct Research” form. STEP 2: Once Anatomical Pathology has signed off, the OR must receive and review all documentation outlined above in 18f, as well as the “Specimen for Research Collection – Special Handling Instructions” form with Anatomical Pathology’s signature of approval. <i>REMINDER: Tissue specimens collected in the Operating Room may NOT be picked up from the Operating Room – all tissue specimens must be sent to VCH Pathology. For further information, please see the guidelines posted on the VCHRI website titled “The Review and Approval of a Research Study Impacting VCH Operating Rooms”.</i>	☐ Yes ☐ No
h) Will blood specimens (not part of standard of care) be collected by <u>ANAESTHESIA</u> during a surgical procedure? If YES, a signature of approval from Anesthesia must be obtained on this form. In addition, the “Specimen for Research Collection – Special Handling Instructions” form must be completed and signed (the timing of the blood collection must be indicated on the form). The instructions noted in 19(g) (Steps 1&2) apply in this case.	☐ Yes ☐ No
i) Will <u>VCH ANATOMICAL PATHOLOGY</u> process tissue specimens collected in the Operating Room or tissue specimens collected in a VCH ward/clinic/community site? If YES, the procedures in 19g (STEP 1 and STEP 2) above must be followed. In addition, the VCH Pathologist involved must be listed as a co-investigator on the research study (on this form and on the UBC ethics certificate).	☐ Yes ☐ No ☐ N/A
j) Does this study involve the utilization of <u>VCH ANATOMICAL PATHOLOGY</u> diagnostic material (e.g. slides, tissue blocks or tissue procurement?) If YES, Anatomical Pathology must review the research study protocol, the “Anatomical Pathology Laboratory Utilization Form”, and sign the “Request for Approval to Conduct Research” form.	☐ Yes ☐ No
k) Does this study involve the collection of specimens (e.g. whole blood, serum, plasma, urine, CSF) that will be used for direct patient care? l) If YES to (k), will the VCH laboratory process the samples and report the results? m) If NO to (l), which laboratory will process the samples and report the results?	☐ Yes ☐ No ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A
20. EXTERNAL RESOURCES: a) Please advise if any procedures, other than those listed above in 19 (k) to (m), will be performed externally and advise who will be performing the procedure and/or analysis:	☐ N/A

21. ADVERTISEMENTS:

- | | |
|--|--|
| a) Will any advertisements for recruitment be posted in a <u>hospital ward/clinic/community site</u> ? (If YES, a signature of approval from the applicable patient service manager of the hospital ward/clinic/community site must be obtained.) | ☐ Yes ☐ No |
| b) Will any advertisements for recruitment be posted in any <u>public/common areas</u> of VCH (e.g. elevators, cafeteria, doors, bulletin boards)? | ☐ Yes ☐ No |
| c) Will study information be sent <u>via email</u> by VCHRI for recruitment purposes (broadcast email)? If yes, please complete the “VCHRI E-Broadcast” form, and send to Stephania Manusha at stephania.manusha@vch.ca | ☐ Yes ☐ No |
| d) Will study information be posted on the <u>VCHRI website</u> under the “Active Research Studies” section of the website? If YES, please complete the “REQUEST TO POST STUDY INFORMATION ON THE VCHRI WEBSITE” form email it to: Stephania Manusha at stephania.manusha@vch.ca If the research study is industry initiated, the “CLINICAL TRIAL RECRUITMENT SPONSOR APPROVAL” form must also be completed. | ☐ Yes ☐ No |

Please remember to include details of all methods of recruitment in your ethics application. If you will be recruiting subjects via the methods listed above in 20(c) or (d), the completed forms must be submitted to the UBC REB for review and approval together with your ethics application before the information is circulated via e-blast or posted on the VCHRI website.

Please submit the following documentation to VCHRI for review:

- ☐ “Request for Approval to Conduct Research” application form with signatures of approval
- ☐ One copy of the UBC ethics board application (NOTE: VCHRI research applications will not be reviewed unless a copy of the ethics board application is provided by the researcher.)

If applicable, please also submit the following documentation:

- ☐ One copy of the informed consent form(s)/letter of initial contact
- ☐ One copy of the “Confidentiality Undertaking for Research Projects” for all research team members
- ☐ One copy of the “Database Access for Research Application Form”
- ☐ One copy of the “OR Research Form” (required for all studies involving surgical procedures)
- ☐ One copy of the “Anatomical Pathology Laboratory Utilization Form” (required for studies involving the services of Anatomical Pathology)
- ☐ One copy of the “Specimen Collection for Research – Special Handling Instructions Form” (required for studies involving the collection of tissue in the operating room)
- ☐ One copy of the Certificate of Ethical Approval. *If at the time the VCHRI application is submitted, ethical approval has not been granted, please submit a copy of the Certificate of Ethical Approval once it is issued by the research ethics board. Ethical approval is required prior to release of the VCHRI research study approval.*

This VCHRI research application should be sent to the following address:

Attention: Wylo Kayle
Willow Chest Centre – Room 163
2647 Willow Street
Vancouver, BC V5Z 3P1

If you have any questions, please contact Wylo Kayle at 604-875-5125 or wylo.kayle@vch.ca

ATTACHMENT A
Confidentiality Undertaking for Research Projects
REB#:

You have requested access to information to be used for your research project (the “**Project**”) and it may contain Vancouver Coastal Health Authority (VCH) patient/client/staff personal information. The collection, use and disclosure of personal information of individuals of VCH are governed by the BC *Freedom of Information and Protection of Privacy Act* (FIPPA). Under FIPPA, it is not permitted to view or access any information that is not required as part of the approved requirements for this Project by the applicable Research Ethics Review Board. Access to confidential or Personal Information (as defined below) is permitted only on a ‘need to know’ basis and limited to the minimum amount of confidential or Personal Information necessary and approved to accomplish this Project (“**Project Information**”).

As a condition of my access to Project Information that is directly accessed or extracted from a database or other source, I acknowledge and agree to the following:

- I confirm that approval of Vancouver Coastal Health Research Institute (VCHRI) and the appropriate Research Ethics Review Board(s) will have been obtained for the Project prior to starting the Project. I understand that a condition of VCHRI approval is agreement to comply with the terms of initial Research Ethics Board Approval and any subsequent terms, as amended from time to time.
- I will access, use and disclose (where permitted) only the minimal amount of “personal information”, as defined in the BC *Freedom of Information and Protection of Privacy Act* (FIPPA) (“**Personal Information**”), necessary for the performance of my duties in connection with the Project.
- If accessing or extracting Project Information from a database, I will only disclose Project Information to individuals who are identified as members of the research team in the Research Ethics Board application or Data Access for Research Project(s) Application Form (the “**Research Team**”) and who have also signed a Confidentiality Undertaking in the same form to this Undertaking.
- I will not disclose any Project Information in personally identifiable form to anyone who is not a member of the Research Team, including in any publication or report containing the results or findings of the Project.
- I will not use the Project Information for the purpose of contacting the individuals to whom the information pertains to participate in the Project or other research, except as approved by the Research Ethics Board or unless the individual has provided written consent.
- I will adhere to the applicable Vancouver Coastal Health Authority (VCH) Information Privacy and Confidentiality Policy and related policies as amended from time to time, concerning the collection, use and disclosure of Personal Information in connection with the Project.
- I will at all times comply with FIPPA and will take reasonable security precautions to protect the Project Information against unauthorized access, collection, use, disclosure or disposal.
- When accessing a VCH database for purposes of the Project, I will comply with any policy, terms of use, confidentiality undertaking or other agreement governing my access to and audit of my access to this database.
- Where Project Information has been provided to me in de-identified form, I will not link the Project Information with other information in a manner that allows for the re-identification of individuals, except as required for the Project and approved by the Research Ethics Board, and VCH Legal Services as appropriate.
- I will immediately report to VCH Information Privacy Office any loss or potential or actual unauthorized disclosure of Project Information.
- After the applicable record retention period has passed, I will promptly destroy all copies of the Project Information or certify as to its destruction, at the direction of VCH.
- I understand that compliance with this Undertaking is a condition of my access to the Project Information and that failure to comply may result in immediate termination of my right to access or possess such information in addition to legal action by VCH.

I have read and agree to comply with the terms stated above. (All research team members must sign this form.)

Name: _____ Title: _____

Signature: _____ Date: _____